

### **Remarks**

Claims 24-43 are presented for the Examiner's review and consideration. Applicant believes the accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

#### **35 U.S.C. §103 Rejection**

Claims 24, 26-29, 31, 34-37, and 39-43 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,669,482 to Shile ("Shile") in view of U.S. Patent No. 6,551,107 to Buckley et al. ("Buckley"). Claims 25 and 32 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Shile in view of U.S. Patent No. 6,058,322 to Nishikawa ("Nishikawa"). Claims 30, 33, and 38 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Shile in view of U.S. Patent No. 6,128,002 to Leiper ("Leiper"). Claim 43 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Shile in view Buckley, and in further view of Official Notice. Applicant submits that the claims are patentable over the cited art for the following reasons.

As discussed in the Submission with the Request for Reconsideration filed on July 13, 2006, Shile relates to a training method for improving diagnostic accuracy and reducing variability in the interpretation of radiologic exams. The training method of Shile is described by which a radiologist's or other exam interpreter's ability to interpret radiologic studies of a patient, whether presented on film, or in a digital format is measured. The method requires that trainees interpret a set of mammograms so that data can be collected.

With respect to the datasets, a first set is representative of the screening environment and is collected from consecutive cases read in a screening practice or group of practices, or by sampling cases from a screening program or group of programs. (Col. 6, lns. 53-57). The sampling produces exams representative of those obtained from a screening referred population. (Col. 6, lns. 57-58). However, since many women undergoing screening mammography have no breast pathology, this dataset should include only those exams that demonstrate findings. (Col. 6, lns. 59-61).

A second test set consists of cases referred from screening mammography for diagnostic evaluation. (Col. 7, lns. 11-12). Exams for this test set should be collected from consecutive cases referred for diagnostic work-up from a screening mammography practice or group of practices. (Col. 7, lns. 15-18). Only cases with confirmed findings are included in this data set. (Col. 7, lns. 22-23).

A third image test set consists of mammograms from patients referred for biopsy. (Col. 7, lns. 35-36). During interpretation sessions with a test set, it may be useful to have findings on exams in the test set clearly identified. (Col. 7, lns. 50-52).

As such, Shile discloses that the data set used in the training method only includes cases with confirmed findings, namely, they only include cases previously examined, i.e., diagnosed cases.

However, the Examiner stated that a broad, yet reasonable, interpretation of Shile does indeed also teach the use of “undiagnosed” real cases for “in-service monitoring” and not just “previously examined” real cases for training purposes. In support, the Examiner asserted that Shile teaches:

The method requires that trainees interpret a set of mammograms so that data can be collected. For a practicing radiologist or other interpreter, these can be mammograms interpreted in the course of their practice ... Alternatively, mammographic test sets can be created to be read by an interpreter.

The Examiner further noted, in particular, Shile’s teaching that real cases can be “interpreted in the course of their practice” (i.e. “in-service monitoring” of “undiagnosed” real cases) or alternatively, test sets of real cases previously examined can be created.

As an initial matter, Applicant submits that as used herein the terms “examined” and “diagnosed” are analogous terms meaning that the case images been screened by a physician or radiologist. Similarly, “unexamined” or “undiagnosed” means that the case images have not previously been screened by a physician or radiologist.

For example Shile recites:

Initially, the radiologist or image interpreter views and interprets a set of radiologic exams. For each viewed image in an examination, a finding is made and the radiologist or image interpreter describes the features of the finding using BI-RADS descriptors. (Col. 5, lns 1-5).

The present invention recites:

When the user starts the screening procedure the program 10 obtains a pseudo-random number from the pseudo-random number generator 11 in order to decide whether the real case i to which the pointer 8 points is to be displayed or if a known cases is to be displayed. It is not transparent to the radiologist whether a case that is currently displayed on the monitor 20 is a real case or a known case. In both instances a diagnosis of the radiologist is entered via the user interface 2 and stored in the database 21. (Page 9)

Accordingly, Applicant submits that the terms “examined” and “diagnosed,” and “unexamined” and “undiagnosed,” are analogous terms and should be afforded the same meaning.

Applicant further submits that the Examiner’s broad interpretation of Shile is incorrect and is directly contradicted in Shile. For example, Shile discloses;

A first set is representative of the screening environment and is collected from consecutive cases read in a screening practice or group of practices, or by sampling cases from a screening program or group of programs. The sampling produces exams representative of those obtained from a screening referred population. However, since many women undergoing screening mammography have no breast pathology, this dataset should include only those exams that demonstrate findings. These can be either benign or malignant findings. (Col. 6, lns. 53-63).

As such, the first data set only include cases with demonstrated finding, either benign or malignant findings, namely, previously diagnosed examined cases.

Similarly, with regard to the Shile’s second data set:

A second test set consists of cases referred from screening mammography for diagnostic evaluation. The representation and distribution of findings in this test set differs from the screening test set and typically contains a larger percentage of malignancies (cancers). .... Only cases with confirmed findings are included in this data set. (Col. 7, lns. 11 – 23).

As such, the cases in the second data set only include cases with confirmed findings, namely, previously diagnosed examined cases.

Shile further recites that:

A third image test set consists of mammograms from patients referred for biopsy. ... During interpretation sessions with a test set, it may be useful to have findings on exams in the test set clearly identified. This can be done by circling findings on the mammographic film, for example, but other means can also be used. (Col. 7, lns. 35 -54).

As such, the cases in the third data set only include cases with confirmed findings, namely, previously diagnosed examined cases, and in fact specifically notes that the findings can be clearly identified for example by circling the finding on the mammogram.

Accordingly, Applicant submits that Shile only discloses using previously diagnosed examined exam images with known findings. Furthermore, the Examiner's broad, yet reasonable, interpretation of Shile is explicitly taught against. As such, Applicant submits that even a broad interpretation of Shile cannot include the use of undiagnosed unexamined cases.

With regard to the citation from Shile. The full citation recites:

The method requires that trainees interpret a set of mammograms so that data can be collected. For a practicing radiologist or other interpreter, these can be mammograms interpreted in the course of their practice, provided that the data discussed below are collected (see Image Interpretation). Alternatively, mammographic test sets can be created to be read by an interpreter.

Applicant notes that this is still directed to a method of training which requires a set of mammograms. The set of mammograms can come from mammograms interpreted by a radiologist or other interpreter in the course of their practice. The term interpreted is past tense, meaning the mammograms have previously been examined. As such, a broad and reasonable interpretation of this paragraph, in view of the remaining disclosure of Shile, would be that the first, second, or third data sets can include cases from a radiologist's or other interpreter's practice which have previously been examined and have known findings or the cases can be created to be read by an interpreter. Any other meaning would be contrary to the direct teaching

of Shile.

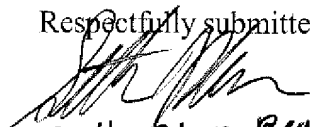
The Examiner further stated that Shile's teaching of a training method is merely one of several preferred embodiments. Applicant traverses the expanded characterization of Shile, noting that the Examiner has failed to provide any support within Shile to reach such a conclusion. Furthermore, and as noted above, Shile provides no disclosure, and specifically teaches against, the screening of real cases, such that Shile cannot be characterized as anything but a training method.

Accordingly, Applicant submits that claims 24, 31, 39, and 40 are patentable over the cited references. Applicant further submits that the dependent claims are also patentable at least for the same reasons.

In light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

No fee is believed due. However, please charge any other required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 500601 (Docket No. 739-X01-004).

Respectfully submitted,

  
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